

Facts and Figures About Clinical Trials

Facts and Figures About Cancer Clinical Trials

The following pages answer some frequently asked questions about the numbers of cancer trials in progress in the United States and the participants in these trials.

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A Note on Web Navigation:

If you are reading this document on-screen, click on the blue text to navigate to a highlighted Web site. (To access this interactive feature your computer must be connected to the Internet, and have Web browser software installed .)

National Cancer Institute Trials

How many National Cancer Institute (NCI) trials are now in progress?

Because NCI supports clinical trials through a variety of funding programs (grants, contracts, cooperative agreements, etc.), there is no single listing or database of all NCI trials and therefore no simple answer to this question. The most comprehensive database of cancer clinical trials is the NCI's PDQ® database, accessible through the NCI Web site CancerNet (<http://cancernet.nci.nih.gov>). PDQ includes most trials sponsored or conducted by NCI. It also includes many cancer trials sponsored by pharmaceutical companies, medical centers, and other groups. It lists both active studies (currently enrolling patients) and those closed to enrollment.

In December 2000, PDQ contains about 1,800 active trials, of which approximately 1,200 are sponsored or conducted by NCI.

Which NCI trials does PDQ include?

PDQ includes most intramural trials – those being conducted by NCI researchers at the National Institutes of Health (NIH) in Bethesda, Md. It also contains many extramural trials — those sponsored by NCI and taking place at cancer centers, hospitals, and community practices around the country.

Of NCI's extramural trials, PDQ includes all that are conducted through the Clinical Trials Cooperative Groups (networks of researchers and institutions with funding from NCI) (http://ctep.info.nih.gov/CoopGroup/Coop_Group_Prog.html). It also includes some of the trials funded through other kinds of funding mechanisms, such as grants and contracts, and trials taking place at NCI-designated cancer centers. (Investigators with grants and contracts funded by the NCI may submit protocols to PDQ but it is not mandatory.)

December 2000 listings in PDQ include:

Intramural trials at the NIH 156
(<http://www-dcs.nci.nih.gov/trials/>)

Extramural trials 1,202
Cooperative Group trials 370
NCI grant supported trials 235
NCI-designated cancer center trials 384

(A variety of other funding mechanisms account for the remaining extramural trials.)

In PDQ, how many NCI trials are there for the four major types of cancer?

For the four types of cancer with the highest number of new cases annually (incidence) and the highest mortality rates, the number of NCI trials listed in PDQ is, as of December 2000:

Lung cancer (non-small cell) 77
Breast cancer (female) 110
Prostate cancer 77
Colon cancer 79

In PDQ, how many NCI treatment, prevention, and other kinds of trials are there?

As of December 2000:

Treatment trials 1,066
Prevention trials 35
Diagnostic trials 50
Screening trials 12
Genetic trials 19
Supportive care trials 79

Can you search PDQ for other categories of trials?

Yes. You can search PDQ on the Internet by the kind of cancer, the phase of the trial, the type or “modality” of treatment (e.g., chemotherapy, vaccine therapy), sponsorship of the trial, and other parameters. Go to <http://cancernet.nci.nih.gov> (click on PDQ). You can also request a search of PDQ by calling NCI’s Cancer Information Service at 1-800-4-CANCER. Health professionals can request a search by contacting the CancerNet Service Center at 1-800-345-3300.

What NCI trials does PDQ not include?

Some NCI-sponsored trials may not appear in PDQ because it is not mandatory for investigators to submit trials to the database. Trials missing from PDQ include some of the trials funded through NCI grants or contracts and some taking place at NCI-designated cancer centers.

Some NCI-designated cancer centers (<http://cancertrials.nci.nih.gov/finding/centers/index.html>) maintain lists of their own clinical trials on their Web sites.

Are there other databases that include NCI trials?

Yes. The National Institutes of Health (NIH), of which NCI is a part, maintains several databases or registries of clinical trials:

- The NIH clinical trials registry (<http://clinicaltrials.gov>) contains all cancer trials that are listed in PDQ.
- The Web site of the NIH Office of Rare Disease (<http://rarediseases.info.nih.gov/ord/>) also contains cancer clinical trials, all of which are also in PDQ.
- The CRISP (http://crisp.cit.nih.gov/crisp_def.html) database lists and describes biomedical research grants and contracts funded by the Department of Health and Human Services, NIH’s parent agency. As of December, 2000, it includes about 300 listings for current, investigator-initiated (R01) grants that involve cancer clinical trials and about 30 contracts for cancer trials. Some, but not all, of the trials in CRISP are listed in PDQ. (CRISP stands for Computer Retrieval of Information of Scientific Projects.)

There are also other Web sites, such as some of those maintained by professional and voluntary groups, that have lists of cancer clinical trials.

Patients in NCI Treatment Trials

How many patients take part in NCI treatment trials?

In recent years, more than 23,000 cancer patients have enrolled annually in NCI treatment trials. This figure includes:

- 20,500 patients in extramural treatment trials carried out by NCI's Clinical Trials Cooperative Groups (networks of physicians and institutions that carry out trials jointly) (http://ctep.info.nih.gov/CoopGroup/Coop_Group_Prog.html). This includes about 5,000 patients enrolled through the Community Clinical Oncology Program, or CCOP, (<http://dcp.nci.nih.gov/corb/ccop.html>) which is a network of 49 central offices in 31 states that provides the infrastructure to link community cancer specialists and primary care physicians with the Cooperative Groups. It also includes patients enrolled through Minority-Based CCOPs (<http://dcp.nci.nih.gov/corb/mbccop.html>).
- 2,500 patients in intramural trials.

How does this break down by gender?

Slightly more men than women enroll in Cooperative Group trials and in intramural treatment trials.

What percentages of adults and children with cancer enroll in NCI Cooperative Group trials?

An analysis (http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=8637047&dopt=Abstract) of trial enrollment in 1991-1994 showed that about 2.5 percent of cancer patients participate in Cooperative Group trials. The percentages for children are much higher than those for adults:

Percentages of cancer patients participating Cooperative Group trials by age:

0-19 years old	71.0%
20-49 years old	4.0%
50 and older	1.5%

Why is the percentage for children so much higher than that for adults?

Experts suggest several reasons:

- Childhood cancer is a rare disease and therefore is often treated in large, specialized or academic treatment centers, where many trials are in progress.
- The physicians who care for children with cancer are familiar with clinical trials and frequently talk to patients and families about trials.
- Most childhood cancers are leukemias and lymphomas, which have included many research opportunities in recent decades; that is, many new treatments have evolved in laboratories and so many clinical trials have been available.

What proportion of older cancer patients enroll in NCI cancer treatment trials?

Several studies have found that older people are under-represented in clinical trials:

- About 1.5 percent of cancer patients age 50 and older are enrolled in NCI Cooperative Group trials, compared to 4 percent of those under 50.
(For an abstract, go to: http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=8637047&dopt=Abstract)
- While 72.4 percent of all men with the more common cancers (lung, prostate, colorectal, pancreas, leukemia) are over age 65, only 39 percent of the patients in NCI Cooperative Group trials fall into this age group.
(For an abstract, go to: http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=8087794&dopt=Abstract)
- Women over 65 make up 56.5 percent of all patients with the more common cancers (lung, breast, colorectal, ovarian, pancreas) but account for only 25.9 percent of patients in Cooperative Group trials for these diseases.
(For an abstract, go to: http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=8087794&dopt=Abstract)
- About 63 percent of cancer patients in the United States are 65 or older. But in one of NCI's large Cooperative Groups – the Southwest Oncology Group – only about 25 percent of clinical trial patients in clinical trials fall in that age group.
(For an abstract, go to: http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10615079&dopt=Abstract)

Why are older people under-represented in clinical trials:

Experts have suggested several possible explanations:

- Research focuses on aggressive therapies, which may be thought unacceptably toxic to the elderly.
- Older people more often have other health problems (co-morbidities) or have had an earlier cancer that bar them from trials.
- Few trials are specifically designed for older patients.
- Physicians, patients and family members may think that older patients are less likely to benefit from and less able to tolerate aggressive treatment.
- Older patients are more likely to be diagnosed with advanced-stage disease, and more trials are designed for early-stage disease.
- Older patients may be less aware of medical developments and less likely to seek out clinical trials.
- There is a lack of financial, logistic and social support for participation of older patients in trials.

What proportion of participants in NCI treatment trials belong to minority groups?

A study (http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=8637047&dopt=Abstract) of participants in Cooperative Group trials found that participation of African Americans and Hispanics was roughly proportional to the incidence of cancer (number of new cases per year) among these groups. Intramural trial statistics are similar.

Minority Representation in NCI Cooperative Group Trials

	<i>% of all participants</i>	<i>% of new cancer cases/year</i>
<i>African American</i>	9.6	9.4
<i>Hispanic</i>	5.6	3.4
<i>Non-Hispanic white</i>	84.8	87.0

Minority Representation in NCI Intramural Trials:

% of all participants

<i>African American</i>	11
<i>Hispanic</i>	2
<i>Asian</i>	2
<i>Non-Hispanic white</i>	85

Physicians in NCI Trials

How many physicians are involved in conducting NCI extramural trials?

About 8,000 physicians in the United States and Canada belong to NCI's Cooperative Groups (http://ctep.info.nih.gov/CoopGroup/Coop_Group_Prog.html). An additional 2,500 community cancer specialists and primary care physicians take part in NCI-sponsored trials through the Community Clinical Oncology Program (<http://dcp.nci.nih.gov/corb/ccop.html>). And about 250 physicians participate in Minority-Based CCOPs (<http://dcp.nci.nih.gov/corb/mbccop.html>).

Where are these physicians located?

These physicians are located in institutions around the U.S. and Canada, including cancer centers, academic or teaching hospitals, and community hospitals.

<i>Cooperative Group institutions:</i>	1,700
<i>CCOP community hospitals:</i>	340
<i>Minority-based CCOP community hospitals:</i>	33

NCI is engaged in a major effort to increase the number of physicians taking part in trials. For more information, go to <http://cancertrials.nci.nih.gov/system/index.html>.

Funding and Costs

How much money does NCI spend on clinical trials and what does it cover?

In fiscal year 1999, NCI spent \$529 million on clinical trials. These funds help pay for some of the costs associated with trials, such as developing concepts; preparing and reviewing protocols; monitoring for safety and accuracy; collecting and analyzing data; and preparing and shipping experimental drugs.

What costs are the responsibility of the patient's health plan?

In extramural trials, the patient's health plan (or the patient) pays for the patient care costs associated with the study. Patient care costs can include, for example, laboratory tests, office visits, and the administration of anti-cancer drugs. Health plans are also expected to cover drugs that are not experimental. These may include supportive medicines, such as anti-nausea drugs. The NCI provides experimental drugs.

Is it more expensive to participate in a trial than to receive standard treatment?

Recent studies (<http://cancertrials.nci.nih.gov/news/features/costs/>) have found that the costs of caring for patients enrolled in clinical trials are not substantially greater than the costs of standard care. Additional larger studies (<http://jnci.oupjournals.org/cgi/content/full/92/14/1116>) are in progress.

Other Sponsors of Cancer Trials

What other federal government agencies sponsor cancer trials?

In addition to the National Cancer Institute, several other institutes at the National Institutes of Health (NIH) sponsor or conduct clinical research related to cancer. For example, the National Heart, Lung and Blood Institute (<http://www.nhlbi.nih.gov/>) has trials for blood-related cancers, such as leukemia, and the National Institute of Diabetes and Digestive and Kidney Diseases (<http://www.niddk.nih.gov/>) has clinical studies for patients with non-beta islet cell tumor, a type of pancreatic cancer, and for prostate cancer. The National Institute of Neurological Disorders and Stroke (<http://www.ninds.nih.gov/>) conducts trials for patients with brain tumors.

Outside NIH, the two major federal agencies carrying out cancer trials are:

Department of Defense (DoD): The DoD's Congressionally Directed Medical Research Program (CDMRP) sponsors research, including clinical trials, in breast cancer. (The CDMRP also sponsors research in prostate, ovarian, and other types of cancer but does not currently have clinical trials in these diseases.) The CDMRP Web site (<http://cdmrp.army.mil>) currently lists 20 grants for breast cancer clinical trials. More information is available on the Web site or from CDMRP's public affairs office, 301-619-7783.

Dept. of Veteran's Affairs (VA): The VA conducts cancer trials at many of its medical centers around the country, funded through its own appropriations as well as through grants from the National Cancer Institute and pharmaceutical companies. The VA currently has nine cancer trials in progress — five large, multi-institution trials and four smaller trials. More information is available via NCI's cancerTrials Web site at <http://cancertrials.nci.nih.gov/beyond/vadod.html>.

What voluntary groups sponsor trials?

Many foundations and other voluntary groups provide funding for cancer research. Major sponsors include:

American Cancer Society (ACS): The ACS supported 49 clinical research projects in 2000, including 12 early (phase I or II) clinical trials. General information on ACS research is available from its Web site at <http://www.cancer.org> and by calling toll-free 1-800-ACS-2345.

Susan G. Komen Foundation: The Komen Foundation sponsors a wide range of research on breast cancer. It provided funding for 16 clinical research projects in 2000, some of which were clinical trials. More information on the foundation is available from <http://www.komen.org> or by calling 972-855-1600.

CaP CURE: Dedicated to research and education on prostate cancer, Cap CURE is sponsoring more than 60 clinical trials in about 12 locations around the country. For more information, including a list of trials, visit <http://www.capcure.org> or call 1-800-757-CURE.

How many pharmaceutical companies are involved in cancer treatment trials?

More than a hundred.

As with government-sponsored trials, there is no single, all-inclusive database of trials sponsored by drug companies and therefore no simple, precise answer to this question. The most comprehensive listing of pharmaceutical and biotech company trials comes from an annual survey on new medicines in development for cancer, published by the Pharmaceutical Research and Manufacturers of America (PhRMA) (<http://www.phrma.org/>). PhRMA does not limit its survey to its own members, but aims to include all drugs in development at U.S. companies and the NCI. More than a hundred different companies appear in PhRMA's most recent survey (1999).

Cancer Drugs in Trials

How many anti-cancer drugs are in clinical trials?

Several hundred. In 1999, for example, there were 354 different drugs in cancer trials, according to a survey on new medicines in development for cancer, published by the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA does not limit its survey to its own members, but aims to include all drugs in development at U.S. companies and the NCI.

How many of these are being developed by or with support from the National Cancer Institute?

For about 150 of the drugs listed, NCI filed the Investigational New Drug (IND) application with the Food and Drug Administration and is now sponsoring or conducting the trials in conjunction with the companies. (An IND must be filed before a drug can be tested in humans.)